Charles Auer

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To: sneha.satya@nicnas.gov.au, raimund.quint@bmu.gv.at, robert.donkers@cec.eu.int, t.lakhanisky@iph.fgov.be, robert.chenier@ec.gc.ca, hasa@env.cz, LSE@mst.dk, Hty@mst.dk, jukka.malm@ymparisto.fi, esa.nikunen@ymparisto.fi, laurence.musset@environnement.gouv.fr, chemg@baua.bund.de, gxk-environment@ath.forthnet.gr, Kozak@mail.ktm.hu, tompa.okbi@antsz.gov.hu, binetti@iss.it, bjorn.hansen@jrc.it, matsuda-tsutomu@mhlw.go.jp, oikawa-shinichi@meti.go.jp, shchung@me.go.kr, dick.sijm@rivm.nl, arnold.vanderwielen@minvrom.nl, Eli.Vike@sft.no, jerzy.majka@chemikalia.mz.gov.pl, matejova.jana@flora.lifeenv.gov.sk, gunnar.Bengtsson@kemi.se, ivar.lundbergh@kemi.se, aitio@who.ch, urs.staempfli@buwal.admin.ch, chemical.management@defra.gsi.gov.uk, auer.charles@epa.gov, hazen.susan@epa.gov, hernandez.oscar@epa.gov, esilberg@jhsph.edu

cc: Mary Dominiak/DC/USEPA/US, Jennifer Seed/DC/USEPA/US, Chris Blunck/DC/USEPA/US, Priscilla Flattery/DC/USEPA/US@EPA, Diane Beal/DC/USEPA/US@EPA

Subject: Preliminary Risk Assessment on Perfluorooctanoic Acid (PFOA)

Dear Members of the OECD Existing Chemicals Steering Group,

On Monday, April 14, 2003, the U.S. Environmental Protection Agency released a preliminary risk assessment on perfluorooctanoic acid (PFOA), a chemical which is structurally similar to perfluorosulfonic acid (PFOS). As you may recall several OECD Member countries collaborated in the preparation of an OECD hazard assessment of PFOS.

This information is being provided to inform you about the current state of EPA's risk assessment efforts on PFOA, which is focused on developmental toxicity as described in the material. The Agency is interested in collecting additional information because new laboratory studies recently evaluated by the Agency show that PFOA, which is used in the manufacture of fluoropolymers, may cause developmental toxicity and other health effects. Further, the available data indicate that the general U.S. population may be exposed to PFOA at very low levels. The potential sources and exposure pathways of PFOA are not well understood at this time. It may be released during manufacturing or processing, and it may also be formed during the environmental breakdown of certain other fluorinated compounds known as telomers. PFOA may also have been a contaminant in certain other fluorinated products (e.g., PFOS) that were largely discontinued by the end of 2002 in the U.S.

Because there remains considerable scientific uncertainty regarding the potential risks from PFOA, EPA considers it important to develop additional data to determine whether subsequent steps would be necessary to protect public health. These data include use and production volume data, information on chemical and product degradation, and additional monitoring of PFOA levels in the environment. The additional data will be used to reduce the scientific uncertainties in the risk assessment, to better understand the potential sources in the environment, and to identify potential exposure pathways. As a positive step, companies that manufacture and use PFOA, as well as companies that manufacture telomers, are taking voluntary product stewardship steps, as described in Letters of Intent submitted to the Agency. Copies of these Letters of Intent are attached to this message.

EPA also encourages the public and other interested parties to identify and generate additional information on PFOA and on fluorinated telomers that may degrade to form PFOA in order to allow the Agency to further develop its risk assessment and to determine whether regulatory action may be appropriate.

EPA published the announcement of these activities in the **Federal Register** on Wednesday, April 16, 2003. Comments on the notice are due on May 16, 2003. A copy of the **Federal Register** notice is attached to this message, together with a copy of the preliminary risk assessment and the letter peer

review of the assessment. The electronic public docket for this action can be accessed through the Internet at www.epa.gov/edocket/ by using the "Quick Search" feature to locate docket OPPT-2003-0012. The Agency is also inviting public participation in the development of enforceable consent agreements (ECAs), which will be used to direct the generation of new scientific information critical to understanding the sources and pathways of potential exposures to PFOA. The public ECA meeting will be held in Washington, DC on Friday, June 6, 2003. Following receipt of additional scientific information, EPA expects to develop a more comprehensive risk assessment that incorporates new information. The Agency then plans to seek additional public comments and independent peer review from the Agency's Science Advisory Board later this year.

EPA prepared a press statement and a fact sheet concerning these activities, and copies of these documents are also attached for your information.

If you have questions concerning this matter, you can contact Mary Dominiak (dominiak.mary@epa.gov ; the technical contact identified in the published notice) or Jennifer Seed (seed.jennifer@epa.gov ; questions relating to the preliminary risk assessment).

The attached files include:

- Press Release
- Fact Sheet (Q&A)
- FR Notice
- Preliminary Risk Assessment
- Peer review on Risk Assessment
- All four industry Letters of Intent


Press Release on PFOA.p

3-14-2003 FMG LOI.pc

3-14-2003 TRP LOI.pc

3-31-2003 Umbrella LOI.p

APFO Prelim RiskAssmt 4-10-200

Final Coded PFOA FR Notice.

PFOA External Letter Peer Review

pfoafcts.pdf

3-13-2003 3M LOI.pc

Charles M. Auer, Director
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW (7401M)
Washington, DC 20460
Phone (202) 564-3810 Fax (202) 564-0575

Deliveries:
EPA-East Building
1201 Constitution Avenue, NW
Room 3166A (7401M)
Washington, DC 20004

United States
Environmental Protection
Agency

Office of Public Affairs
Washington D.C. 20460
(1703A)

Office ph. 202-564-4355
www.epa.gov/newsroom

Environmental News

FOR RELEASE: MONDAY APRIL 14, 2003

EPA INTENSIFIES SCIENTIFIC INVESTIGATION OF A CHEMICAL PROCESSING AID

Contact: David Deegan, 202-564-7839/deegan.dave@epa.gov

Today EPA is releasing a preliminary risk assessment for the chemical PFOA and is encouraging the public and other interested parties to participate in identifying and generating additional information that will allow the Agency to further develop its risk assessment. PFOA, also known as perfluorooctanoic acid, is used as a processing aid in the manufacture of a wide variety of consumer and industrial products, and may also be formed during the environmental breakdown of related chemicals. Studies recently evaluated by the Agency have raised a number of potential toxicity concerns, and when combined with information that the general U.S. population may be exposed to very low levels of PFOA, has led the Agency to conclude that additional scientific information is needed to determine if new regulatory actions are necessary.

"To ensure consumers are protected from any potential risks, the Agency will be conducting its most extensive scientific assessment ever undertaken on this type of chemical," said Stephen L. Johnson, Assistant Administrator of EPA's Office of Prevention, Pesticides, and Toxic Substances. "Today's announcement puts in place rigorous regulatory and scientific steps that will lead to a better understanding of PFOA. This priority scientific review will guarantee that any future regulatory action on PFOA is protective of public health and supported by the best scientific information."

To initiate this process, the Agency is releasing its preliminary risk assessment on PFOA for public review. A public docket has been established so interested parties can review the scientific information available to the Agency. Similarly, through public meetings, the Agency is inviting participation in the development of enforceable consent agreements, which will be used to direct the generation of new scientific information critical to understanding the sources and pathways of potential exposures to PFOA. By using enforceable consent agreements, the generation of new data can be accelerated so the data is available quickly. Following receipt of additional scientific information, EPA expects to develop a more comprehensive risk assessment that incorporates new information. The Agency then plans to seek additional public comments and independent peer review from the Agency's Science Advisory Board later this year.

The Agency is interested in collecting additional information because a new laboratory studies recently evaluated by the Agency shows that PFOA may cause developmental toxicity and other health effects. Further, the available data indicate that the general U.S. population may be exposed to PFOA at very low levels. The potential sources and exposure pathways of PFOA are not well understood at this time. It may be released during manufacturing or processing, and it may also be formed during the environmental breakdown of certain other fluorinated compounds known as telomers. (Telomers are small fluorinated polymers.) PFOA may also have been a contaminant in certain other fluorinated products that were discontinued by the end of 2002.

Because there remains considerable scientific uncertainty regarding the potential risks from PFOA, it is important to develop additional data to determine if subsequent steps are necessary to protect public health. These data include use and production volume data, information on chemical and product degradation, and additional monitoring of PFOA levels in the environment. The additional data will be used to reduce the scientific uncertainties in the risk assessment, to better understand the potential sources in the environment, and to identify potential exposure pathways.

Given these considerable scientific uncertainties, EPA has not made a determination as to whether PFOA poses an unreasonable risk to the public. This determination will be better informed as new exposure data are factored into the risk assessment. EPA does not believe there is any reason for consumers to stop using any consumer or industrial related products.

As a positive step, companies that manufacture and use PFOA, as well as companies that manufacture telomers, are taking voluntary product stewardship steps, as described in Letters of Intent submitted to the Agency. These letters are available in the public docket. For example, 3M will not resume the manufacture of PFOA, and they will continue medical monitoring efforts for workers and continue monitoring groundwater, surface water, and other environmental media and provide reports to EPA. The members of the Fluoropolymer Manufacturers Group have committed to reduce emissions, to study their products to determine whether they may be a source of PFOA, and to take steps to reduce exposures to workers and the environment. The members of the Telomer Research Program have committed to evaluating products sold in the U.S. to determine whether they contribute to significant human or environmental exposure to PFOA.

By way of background, PFOA is used as an essential processing aid in the manufacture of fluoropolymers. Fluoropolymers are used in a wide variety of consumer and industrial applications, including non-stick surfaces on cookware, but finished products are not expected to contain PFOA. PFOA may also be a degradation product of small polymers called telomers, which are used in a range of commercial products including fire fighting foams, as well as soil, stain and grease resistant coatings on carpets, textiles, paper, and leather.

For further information on EPA preliminary risk assessment of PFOA, including the Federal Register notice, Fact Sheet and Questions & Answers, please visit http://www.epa.gov/oppt/.

R-099 # # #

EPA FACT SHEET

Public Q's & A's on PFOA

*In a **Federal Register** notice signed on April 14, 2003, EPA is releasing a preliminary risk assessment for the chemical PFOA, and is starting a public process to identify and generate additional information to strengthen the risk assessment. EPA is also inviting interested parties to monitor or participate in negotiations on one or more enforceable consent agreements to obtain additional data concerning PFOA and fluorinated telomers which may metabolize or degrade to PFOA. The first public meeting will take place on June 6, 2003.*

1. What is PFOA?

PFOA is perfluorooctanoic acid. It is a synthetic (man-made) chemical and does not occur naturally in the environment. The "PFOA" acronym is used to indicate not only perfluorooctanoic acid itself, but also its principal salts. The most commonly used chemical in this grouping is the ammonium salt, ammonium perfluorooctanoate, or APFO, which is sometimes called "C8."

2. What is PFOA used for?

PFOA is used as an essential processing aid in the manufacture of fluoropolymers. Fluoropolymers impart valuable properties, including fire resistance and oil, stain, grease, and water repellency. For example, they can be used to provide non-stick surfaces on cookware and protective finishes on carpets and clothing. They are employed in hundreds of uses in almost all industry segments, including the aerospace, automotive, building/construction, chemical processing, electrical and electronics, semiconductor, and carpet and textile industries. Although fluoropolymers are made using PFOA, the finished products themselves are not expected to contain PFOA.

3. What action is EPA taking?

EPA is issuing a preliminary risk assessment of PFOA, requesting public comment on its scientific findings, and seeking additional data concerning these chemicals. EPA is also inviting interested parties to monitor or participate in negotiations on one or more enforceable consent agreements (ECAs) under section 4 of the Toxic Substances Control Act (TSCA) concerning PFOA and fluorinated telomers which may metabolize or degrade to PFOA. EPA is also announcing the first public meeting for these ECA negotiations, which will be held on June 6, 2003. EPA is taking these steps to better understand the sources and exposure pathways leading to the presence of PFOA in human blood. Further information will help EPA determine whether and what additional actions are appropriate.

4. Why is this action necessary?

The Agency is interested in collecting additional information because studies have indicated that PFOA causes developmental toxicity and other effects in animals. EPA's preliminary assessment indicates potential exposure of the U.S. general population to PFOA at very low levels. However, this assessment also reflects considerable scientific uncertainty regarding the potential risks. EPA has identified areas where additional information could be very helpful in allowing the Agency to develop a more accurate assessment of the potential risks posed by PFOA and by chemicals that may degrade to form PFOA, and to identify what voluntary or regulatory actions, if any, would be appropriate.

5. Are there steps consumers could take to reduce exposures to PFOA?

At present, there aren't any steps that EPA recommends that consumers take to reduce exposures to PFOA, because the sources of PFOA in the environment and the pathways by which people are exposed are not known. Given the considerable scientific uncertainties, EPA has not made a determination as to whether PFOA poses an unreasonable risk to the public. This determination will be better informed as new exposure data are factored

into the risk assessment. EPA does not believe there is any reason for consumers to stop using any consumer or industrial related products.

6. How are people exposed to PFOA?

Current information indicates that the general U.S. population may be exposed to very low levels of PFOA, but the available scientific information cannot determine how people are being exposed. The limited geographic locations of fluorochemical plants making or using the chemical suggest that there may be additional sources of PFOA in the environment, and exposures beyond those attributable to direct releases from industrial facilities. The degradation of telomer chemicals may be one of these additional sources. But whether human exposures are due to PFOA in the air, the water, on dusts or sediments, in dietary sources, or through some combination of routes is currently unknown.

7. What types of industrial and consumer products contain PFOA?

Currently, consumer products are not believed to contain PFOA, although some products might contain other chemicals, called telomers, that might degrade over time in the environment to form PFOA. Some industrial fluoropolymer dispersion products contain PFOA, but these products are typically used in heat-treated applications that would remove the PFOA from final products before they leave the manufacturing plants.

8. What are fluorinated telomers, and how do they relate to PFOA?

Fluorinated telomers, commonly called "telomers," are small fluorine-containing polymers, man-made chemicals produced by a specific process that utilizes the ability of certain chemicals to link together into chains of a defined length. Although telomers aren't made using PFOA, some data indicate that certain telomers may break down or degrade to form PFOA in the environment, and may be metabolized to form PFOA if they get inside living organisms.

9. What are telomers used for?

Telomers are used in many products, including fire fighting foams; personal care and cleaning products; and oil, stain, grease, and water repellent coatings on carpet, textiles, leather, and paper.

10. Are there reasonable and cost effective alternatives to PFOA and telomers?

PFOA is an essential processing aid in the manufacture of fluoropolymers. Fluoropolymer manufacturers have indicated that there are no known alternatives to PFOA. Some manufacturing processes can use different technologies that don't employ PFOA, but these processes could not currently be used to produce most fluoropolymer products.

EPA does not know all of the uses of the telomer chemicals, and thus does not have readily available information concerning alternatives for those uses. The industry has committed to provide additional information as part of its ongoing voluntary activities with respect to these chemicals.

11. What companies manufacture PFOA and telomers?

3M Company formerly manufactured PFOA in the United States, but discontinued manufacturing the chemical during the period 2000-2002. Currently, DuPont is the only domestic manufacturer of PFOA. Other companies may manufacture PFOA elsewhere in the world.

DuPont, Clariant GmbH, Daikin Industries, and Asahi Glass all manufacture telomers at various facilities worldwide. There may be additional producers of telomer chemicals.

12. What exactly is an ECA?

An enforceable consent agreement (ECA) is a publicly negotiated agreement among EPA, industry, and interested parties that requires certain signing parties to generate data and submit those data to EPA on a specified schedule. EPA has found that, in instances where there is substantial agreement that particular data are necessary or important, ECAs can be a much quicker way to obtain data than pursuing a test rule under section 4 of the Toxic Substances Control Act. Test rules can take up to two years to complete, while ECA's can often be concluded in less than a year. ECAs are enforceable, meaning that EPA can compel the submission of information agreed to under the ECA. Because they are negotiated in public, all parties who are interested in the data have the opportunity to participate.

13. Is PFOA more toxic to children than to adults?

EPA is not aware of any studies that would provide evidence that PFOA is either more or less toxic to children than to adults.

14. Is PFOA present in my food, drinking water and indoor air?

EPA does not know the source of PFOA in the environment, or the pathways by which it is getting into humans. There are only very limited data on the general environmental presence of PFOA. Additional studies are attempting to determine answers to these questions.

15. What are the health benefits from EPA taking this action?

EPA's preliminary assessment indicates that the general U.S. population may be exposed to PFOA at very low levels. Receiving the information that EPA has requested will allow the Agency to better characterize the exposure, refine its risk assessment, and determine what additional actions, if any, would be appropriate to protect human health and the environment.

16. What additional data is the Agency requesting and why?

EPA is asking for use and production volume data, to better define the universe of chemicals which may contribute to the presence of PFOA in the environment and in people, and additional data on chemical and product biodegradation to help explain the sources of PFOA. EPA is also requesting any additional information that would help in the development of an understanding about the pathways by which people may be exposed to PFOA.

17. What are the next steps to evaluate PFOA?

EPA has requested additional information that would help to reduce the uncertainties in its scientific risk assessment and improve the understanding of the presence of the chemical in the environment. EPA expects to submit a more comprehensive risk analysis incorporating some of this additional information to the Agency's Science Advisory Board for independent peer review and comment in Fall 2003. EPA has also solicited interested parties to participate in the negotiation of enforceable consent agreements to produce additional data. Industry has already committed to providing some additional information through letters of intent submitted to the Agency in March 2003.

18. What is a Letter of Intent?

A Letter of Intent is a unilateral statement by a company, group, or individual describing activities they are undertaking, and making voluntary commitments to perform those activities as described. Because the commitments in such a letter are voluntary, the letters are not binding or enforceable.

19. What has industry committed to do in their letters of intent on PFOA and telomers?

In brief, the companies have committed to providing additional data that should help to develop the understanding of PFOA sources and exposures. 3M Company has indicated that it will not resume the manufacture of PFOA, and it will continue its medical monitoring efforts for workers and continue monitoring groundwater, surface water, and other environmental media and provide reports to EPA. The members of the Fluoropolymer Manufacturing Group have committed to reduce emissions, to study their products to determine whether they may be a source of PFOA, and to follow principles of product stewardship in their efforts to support toxicological research, control occupational exposures in their own facilities, monitor employee health, assist customers in protecting their employees, and meet the general commitment to reduce emissions to the environment. The members of the Telomer Research Program have committed to evaluating telomer products sold in the U.S. to determine whether they contribute to significant human or environmental exposure to PFOA. All of the Letters of Intent are available in the public docket.

FOR MORE INFORMATION:

For general information about PFOA, or about these standards, contact:

*TSCA Hotline 202-5541404

* EPA's web site at *www.epa.gov/oppt/*